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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/748,625

12/27/2003

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7504

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07/09/2007

EXAMINER

ROGERS, JAMES WILLIAM

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

07/09/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/748,625	Applicant(s) SHAH, KISHORE R.	
	Examiner James W. Rogers, Ph.D.	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 9,12-15,19 and 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-8,10-11 and 16-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05/30/2007 has been entered.

Claim Objections

Claims 1-3,11,16-17 are objected to because of the following informalities: there is no need to capitalize the word "Copolymer". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-11 and 16-18 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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Claims 1,11 and 16-17 all recite that the compositions comprise a graft copolymer comprising a hydrophilic polymer chain comprising monomeric units, some of which have acidic groups. The specification does not provide enough written support to claim any hydrophobic polymer that has an acidic group. The only acidic monomers described within the specification that have acidic groups are acrylic and methacrylic acids, 2-acrylamido-2-methyl-propane sulfonic acid, 2-sulfoethyl methacrylate, and vinyl phosphonic acid, therefore the specification only provides written support for the above acidic monomers. It is suggested by the examiner that in order to remove this rejection applicants amend all independent claims to include a Markush group of the following acidic monomers acrylic and methacrylic acids, 2-acrylamido-2-methyl-propane sulfonic acid, 2-sulfoethyl methacrylate, and vinyl phosphonic acid which are supported within the specification.

Also claims 1,11 and 16-17 recite that the composition comprises a water-soluble polymer, the specification does not provide enough written support to claim all water soluble polymers known in the art. Instead the specification details specific polymers that can be combined with the graft copolymers, those polymers include poly(N-vinyl 2-pyrrolidone), hydroxypropyl cellulose, xanthan gum, hydroxyethyl cellulose, and poly(N,N-dimethylacrylamide). It is suggested by the examiner that in order to remove this rejection applicants amend all independent claims to include a Markush group of the following water soluble polymers poly(N-vinyl 2-pyrrolidone), hydroxypropyl cellulose, xanthan gum, hydroxyethyl cellulose, and poly(N,N-dimethylacrylamide) which are supported in the specification.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 16-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically all of the claims above recite the limitation that the composition comprises a hydrophilic or hydrophobic carrier or mixtures thereof. This limitation is so broadly written that it is not clear what applicants are specifically claiming, a hydrophobic or hydrophilic carrier can read on just about any ingredient within a composition, thereby making the limitation nearly unsearchable and one with skill in the art would not be appraised of applicants claimed invention and its scope. It is suggested by the examiner that applicants bring in through amendment some specific examples supported within the specification (Markush group) on what materials would satisfy a hydrophilic and hydrophobic carrier.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8,10-11,16-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Shah et al. (US 5,527,271).

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Shah teaches a thermoplastic hydrogel impregnated composite material which contains a hydrogel polymer including up to 40% preferably 2-20% of a graft copolymer such as poly(2,3-dihydroxypropyl methacrylate-g-styrene), 15 to 60% plasticizer (including PEG a water soluble polymer) and lubricity improving agents. See col 2 lin 54-col 5 lin 13 claims and examples. Regarding the limitation that the composition is a homogenous dispersion, Shah clearly states that the hydrogel polymers and plasticizer are stirred until a homogenous solution is formed and then allowed to dry, and then immersed in water for 24 hours, thus it is inherent that since the graft copolymers were homogeneously mixed with the plasticizer the hydrogel would be a homogenous dispersion. Regarding claims 7-8 that require a biologically active ingredient, Shah teaches the use of lubricity enhancing ingredients such as pectin which has well known biological activities such as its use against constipation and diarrhea and as a demulgent.

Response to Arguments

Applicant's arguments filed 05/30/2007 in regards to Morrissey et al. (US 6,106,820) have been fully considered and are persuasive because as applicants have argued the appended blocks of the graft-copolymers of Morrissey are hydrophilic or a mixture of hydrophilic and hydrophobic monomers provided that the overall macromonomer is hydrophilic. The rejection over Morrissey has been withdrawn by the examiner.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4,6-8,10-11,16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shah (US. 5,942,243, cited by applicant), for the reasons set forth in the office action dated 09/21/2006 and 01/26/2007.

Claims 1-8,10-11,16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shah (US. 5,942,243, cited by applicant) in view of Morrissey et al. (US 6,106,820), for the reasons set forth in the office action dated 09/21/2006 and 01/26/2007.

Applicant's arguments filed 05/30/2007 have been fully considered but they are not persuasive. Applicants assert through arguments and declaration that Shah does not disclose a homogenous composition as currently claimed. Applicants also stated the following unexpected result, "it was discovered upon homogenization by a laboratory blender or homogenizer that the hydrogel formed a very stable dispersion which is almost "solution like" and has a slight bluish haze".

First the examiner will comment on the recitation of unexpected results, while the examiner has full confidence that applicants have added an additional step of homogenation by the use of a blender or homogenizer to the process of making the composition then described within 5,942,243 ('243 from hereon), the examiner must examine the claims as being drawn to a composition that is homogenous. If the

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composition is the same and it is homogenous then the process to make it does not bear any patentable weight, in fact as currently amended the claims do not even recite a product by process type of limitation for the claimed composition. Therefore the recitation of unexpected results by a process of homogenization bears little weight on the claimed invention to a composition. Secondly applicants arguments and declaration stating that the compositions of '243 do not recite a homogenous composition are not found persuasive. While the examiner believes that applicants declaration is bona-fide it is considered an opinion declaration because it does not provide any working examples that shows the compositions envisioned in '243 are not homogenous. From within '243 it states clearly when formulating the pharmaceutically active agent with the other components is achieved by dissolving all of the components and evaporating the solvent under vacuum or alternatively the components can be homogenously mixed in the melt in a conventional processor such as an extruder or sigma blade mixture. See col 5 lin 19-22 and col 6 lin 52-63. It is apparent to the examiner and it would have been obvious to one skilled in the art that the above techniques for formulation would result in a homogenous mixture of the same ingredients as claimed by applicant, therefore the limitation is met. As already stated above since the claims are drawn to a composition and not the process to make it applicants claimed invention is met by '243 which discloses homogenous compositions containing all of applicants claimed ingredients.

Conclusion

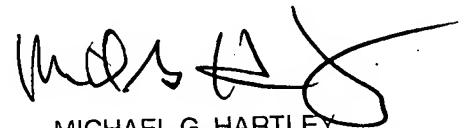
No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D.

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whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Michael G. Hartley', with a large, stylized flourish at the end.

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER